

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

The Effectiveness of Green Tea on Post operation Relaxation and Pain in Tibia Surgery

Protocol summary

Summary

The aim of this study is comparing the changes of VAS score and BRS before receiving green tea and 8 hrs after operation. This clinical trial is performed on patients undergoing tibia surgery in Poorsina hospital in Rasht, Iran. After obtaining a history, physical exam and 12 lead ECG, venous blood is obtained for baseline biochemical serum measurements, as well as CBC- ALT- AST- BUN- Cr-ALKP. The inclusion criteria are the patient aged between 30-65 years old candidate for tibia fracture surgery daily consumed of black tea are not more than 2 tea bags or 4g loose tea/day. The exclusion criteria are cognitive or psychiatric disorders; history of any drug abuse, hepatic and renal diseases; pregnancy and breast feeding. All participants meeting inclusion criteria provided with informed consent. In this double blind clinical trial participants are randomly assigned to two groups of green tea and placebo by triple blocks. The anesthesia method and pain control are the same in two groups, green tea (n=30) and placebo (n=30). In green tea group, patients receive a cup of green tea 2hrs before and 6hrs after operation. In two groups pain severity and relaxation are evaluated based on VAS score and BRS by a person who is not aware of the type of drink .Then the results will be compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201504076186N9**

Registration date: **2015-04-09, 1394/01/20**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-04-09, 1394/01/20

Registrant information

Name

Bahram Naderi Nabi

Name of organization / entity

Guilan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2015-12-10, 1394/09/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Green Tea on Post operation Relaxation and Pain in Tibia Surgery

Public title

Effect of Green Tea on Relaxation and Pain

Purpose

Prevention

Inclusion/Exclusion criteria

The inclusion criteria are the patient aged between 30-65 years old candidate for tibia fracture surgery; daily consumed of black tea are not more than 3 tea bags or 4

diluted ones. The exclusion criteria are cognitive or psychiatric disorders; history of any drug abuse; hepatic and renal diseases; pregnancy and breast feeding.

Age

From **30 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

Shahid Beheshti Freeway

City

Rasht

Postal code

4193833697

Approval date

2015-02-24, 1393/12/05

Ethics committee reference number

1930596705

Health conditions studied

1

Description of health condition studied

pain and relaxation

ICD-10 code

Y55.1

ICD-10 code description

Skeletal muscle relaxants [neuromuscular blocking agents]

Primary outcomes

1

Description

Pain

Timepoint

2 hours before surgery and 6 hours after surgery

Method of measurement

VAS score

2

Description

Relaxation

Timepoint

2 hours before operation and 8 hours after operation

Method of measurement

Behavior Relaxing Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention 1) Green Tea, a cup of tea; two hours before and 6 hours after surgery.

Category

Treatment - Drugs

2

Description

Intervention 2) A cup of warm water; two hours before and 6 hours after surgery.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Poursina Hospital

Full name of responsible person

Bahram Naderi Nabi

Street address

Porsina Hospital

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Guilan University of
Medical Sciences

Full name of responsible person

Abtin Heidarzadeh

Street address

Shahid Beheshti Freeway

City

Rasht

Grant name

Grant code / Reference number

**Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Vice chancellor for research of Guilan University of
Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Other areas of specialty/work

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Degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty